CRCPD's Committee on Mammography

Conference of Radiation Control Program Directors, Inc. (CRCPD)
A Partnership Dedicated to Radiation Protection

3503 '99 JUN 16 A9:10

June 15, 1999

Docket No. 99D-0302
Dockets Management Branch
Division of Management Systems and Policy
Office of Human Resources and Management Services
Food and Drug Administration
5630 Fishers Lane Room, 1061 (HFA-305)
Rockville, MD 20852

Dear Dockets Management Branch:

The following are recommendations from the Conference of Radiation Control Program Directors, Inc.'s (CRCPD) MQSA Working Group on the proposed *Compliance Guidance, The Mammography Quality Standards Act Final Regulations, Document #2*, released for comment on March 19, 1999. The MQSA Working Group is comprised of the members of CRCPD's Committee on Mammography: Jennifer Elee, Chairperson (Louisiana), Aaron Gantt (South Carolina), Kathleen Kaufman (California), Bruce Matkovich (Michigan), John McCrohan (FDA Liaison); certified MQSA inspectors from state radiation control programs: Warren Freier (North Dakota), Shanna Hellmuth (Arizona), Judy Koch (Texas), Daniel Oakey (Florida), Linda Plusquellic (Maine), Joyce Zeisler (New Jersey); and FDA inspectors: Robert E. Davis (Pennsylvania), Lynn Jenkins (Illinois), and Michael J. Leal (Massachusetts).

Inspections - General

In the sentence, "If any findings have not been corrected or have recurred since a facility's last MQSA inspection, they are identified as Repeat Findings" recommend deletion of "since a facility's last MQSA inspection." It should not be limited to the last inspection.

It is also recommended that some mechanism be in place to deal with Level 3s repeated over multiple inspections.

Definitions
21 CFR 900.2(z)

In the last sentence of the first answer, add "and requires additional training" so the sentence would read "Implant imaging represents an application of a mammographic modality to patients with breast implants and requires additional training."

Office of the Committee Chairperson
Jennifer G. Elee

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21 CFR 900.2(xx)

Recommend that a sentence be added to indicate that calibration requirements apply only to physicist equipment; however, the facility is ultimately responsible.

Personnel - General

21CFR 900.12(a)

In the response to the question, "Are there any MQSA qualifications related to the people providing general servicing of the mammography equipment," recommend the answer be changed to read "No. Facilities are still responsible for maintaining the equipment performance."

Recommend adding additional guidance for what is acceptable film-screen education training.

In the answer "In the case of medical physicists, the continuing education requirement is to have "hours of training appropriate to each mammographic modality evaluated" but no specific numerical value is given," recommend adding the following sentence, "While some of the continuing education may be in general medical physics, some portion must be related to mammography."

21 CFR 900.12(a)(2)(iv)(A)

In the second to last paragraph, recommend changing the last sentence to read, "However, the provision of summary letters, tables, or printouts will speed up the inspection process and the more detailed records may not be requested." This deletes "rarely will" and inserts "may not" before "be requested."

21 CFR 900.12(a)(3)(ii)

In the answer to the question, "What are acceptable methods for documenting medical physicist initial and continuing experience?" recommend in the second sentence inserting "or from the physics consulting company providing the service" so the sentence would read "Although the survey reports themselves can be used as documentation, in general a summary document such as a letter or memorandum from the facility where the survey was performed or from the physics consulting company providing the service will be sufficient."

In the ACCEPTABLE DOCUMENTS FOR MEDICAL PHYSICISTS chart, the requirement "Survey Training-final regs" is in conflict with GGP1 and needs to be corrected.

Equipment

21 CFR 900.12(b)(3)

Recommend inserting "tube" before "image receptor assembly."

Recommend adding the following sentence at the end of the first paragraph of the answer: "The tube image receptor assembly stays in position it was set when power goes off even if it can be manually moved. It is permissible for the unit to be moved by operator intervention after power disruption."

Recommend inserting "If a modification is required, it does not have to be a manufacturer modification" as a third paragraph.

Recommend the text on motion of tube-image receptor assembly from the Compliance Guidance document The Mammography Quality Standards Act Final Regulations Motion of Tube-Image Receptor Assembly be incorporated into GGP2.

Recommend that within The Mammography Quality Standards Act Final Regulations Motion of Tube-Image Receptor Assembly in the answer to the question, "How much tube-image receptor assembly motion is acceptable before a unit would be noncompliant with 900.12(b)(3)(ii)?" delete the sentence "The amount of acceptable motion is dependent on the circumstances in each facility and should be evaluated on an individual basis."

21 CFR 900.12(b)(5)(ii)

In the second paragraph of the answer to the first question, recommend the sentence read "Instrumentation used should be appropriate for the purpose." Recommend deletion of the rest of that sentence, "and it is suggested that the aperture of the measuring device have a diameter of one millimeter or less."

21 CFR 900.12(b)(8)(ii)(B)

In item number 2 of one acceptable method for performing the compression paddle deflection test, insert "be": "The support plate should be made of..."

21 CFR 900.12(b)

In the question, "Are there any regulations regarding viewbox luminance?" recommend that "viewbox" be deleted.

21 CFR 900.12(c)(1)(vi)

In the answer to the third question, insert "addendum" so the last sentence reads, "If the "addendum" merely stated that the referring health care provider had been notified of the results of the patient's examination, the addendum lay summary could be a simple statement..."

21 CFR 900.12(c)(2)

In the answer to the third question, insert "addendum" so the last sentence reads, "If the "addendum" merely stated that the referring health care provider had been notified of the results of the patient's examination, the addendum lay summary could be a simple statement..."

In the answer to the fourth question, following "give the patient the most complete and useful information" add the following sentence: "The lay summary is only required for mammography procedures."

21 CFR 900.12(c)(4)(i) and 21 CFR 900.12(c)(4)(ii)

Recommend inserting a new #1: "Notify your state radiation control program."

Recommend changing #3 to the #2 position and changing "Attempt to make arrangements" to "Arrange to transfer..."

Following "...facilities could store the medical records in a hospital, if appropriate, or make arrangements to warehouse the records" recommend inserting "The facility should make sure there is a mechanism available to release the films to the patient when requested."

21 CFR 900.12(e)(1)

In the answer to the question, "Must a facility perform the daily processor QC tests on days when mammograms are performed but not processed?" recommend the following sentence be added at the end of the answer, "FDA encourages that films be processed as soon as possible to avoid problems with latent image fading."

21 CFR 900.12(e)(2)

In the first question, recommend changing "reestablish" to "establish."

For the answer to this first question, recommend insert following "servicing of the unit" "Before changing operating levels, check to be sure there isn't some underlying problem that needs to be corrected."

Mammography Medical Outcomes Audit

21 CFR 900.12(f)(1)

For the answer to the second question, following "for all interpreting physicians at that facility" recommend inserting "If physicians read at more than one facility, it may be beneficial to analyze all facilities collectively, although each facility would still have to maintain its own analyzes.

Phantom Image - Level 1 Findings
Procedure for AMR - Phantom Image
Follow-up Actions by FDA with the Facility

Recommend deletion of last sentence of 4.a.: "The review should extend back to the most recent date..."

Recommend deletion of 4.b.: "If none of the facility's weekly QC phantom images..."

Following 4.e., for clarification, recommend adding a second note: "AMRs can be required as determined by the agency. This may include but not be limited to Level 2 findings."

Interpreting Physician - Level 1 Findings
Procedure for AMR - Interpreting Physician
Follow-up Actions by FDA with the Facility

In the second sentence of #4, recommend you look into changing "should" to "must. "The facility must generate..."

Sincerely yours,

Jennifer Elee

Jennifer Elee, Chairperson
Committee on Mammography and MQSA Working Group

JE:LC:lcg

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